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THE HISTORY OF ALCOHOLIC BEVERAGE LABELING REGULATION  
AND ITS

IMPLICATIONS FOR A HEALTH CLAIM ON WINE LABELS

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## Introduction

Alcohol regulation has a long and storied history in the United States. While prohibition is probably the most well known event in that history, there is also an interesting and complex story to be told about the regulation of alcohol labeling. For over 50 years, two government administrative agencies, the Food and Drug Administration (FDA) and the Bureau of Alcohol, Tobacco and Firearms (ATF), and their precursors, have both competed and cooperated in the regulation of alcoholic beverage labeling. This complex agency interaction has important implications for any attempt to add a health claim on wine labels noting the connection between moderate consumption of wine and reduced risks of heart disease.

This paper has two main goals. First, it will provide a history of the FDA-ATF relationship with regard to jurisdiction over alcoholic beverage labeling regulation. This part of the paper will be largely descriptive in nature and will relate the areas in which the two agencies have competed and cooperated. Second, the paper will consider the possibility of adding a health claim to wine labels. This part will analyze both the FDA's regulation of health claims on food labels and recent revisions of the FDA's statutory mandate in order to explore the possibility of gaining government approval for a wine health claim.

## Section I. Jurisdictional Conflict and Cooperation

While Washington is the scene of many great political dramas, some of the most interesting and least publicized are those that occur between administrative agencies. The history of alcoholic beverage labeling regulation has been profoundly affected by the periods of conflict and cooperation between the FDA and the ATF. This awkward inter-agency relationship has occurred because Congress has granted both agencies the jurisdiction to regulate alcoholic beverage labels at various times during the 20th century. Though the two agencies have

attempted to resolve this jurisdictional overlap themselves by means of memorandums of understanding, this has not prevented court involvement in the process. This first part of the paper will explore the relationship between the FDA and the ATF with respect to alcohol labeling regulation so that its implications for the labeling of a health claim on wine can be explored in the second part which follows.

#### A. Congressional and Executive Mandates

The federal government's involvement in the regulation of the food supply began with the passage of the Federal Food and Drug Act of 1906.<sup>1</sup> This act, which among other things prohibited the misbranding of food, defined food to include articles used for...drink. . .by man.<sup>2</sup> Subsequent court cases confirmed that this definition of food did indeed include alcoholic beverages.<sup>3</sup> The Food, Drug and Insecticide Administration (later shortened in name to the FDA) was created in 1927 to administer this act. The 1938 Food, Drug, and Cosmetic Act (FDCA)<sup>4</sup> continued to use the 1906 definition of food and §343(i) of this new act required ingredient labeling for all foods which did not conform to a standard of identity. Since the FDA never issued standards of identity for alcoholic beverages, this section mandated ingredient labeling of alcoholic beverages. Thus, it was clear that Congress originally intended alcoholic beverages to be subject to the same regulation as the rest of the food supply and that the FDA

34 Stat. 768 (1906); 21 U.S.C. c. 1.

<sup>2</sup> *Id.*, §6.

<sup>3</sup> *United States v. 36 Bottles of London Dry Gin*, 210 Fed. 271 (CA-3, 1914); *United States v. 60 Barrels of Wine*, 225 Fed. 846 (D.C. W.D. Mo. 1915); *United States v. Five Cases of Champagne*, 205 Fed. 817 (D.C. N.D.N.Y. 1913); *United States v. 50 Barrels of Whiskey*, 165 Fed. 966 (D.C. Md. 1908).

<sup>4</sup> 52 Stat. 1059 (1938).

had the authority to administer this regulation.

Prohibition resulted in a separate line of regulation of alcoholic beverages, however, that grew out of executive branch action. After the repeal of Prohibition by the Twenty-First Amendment in 1933, the Roosevelt administration wanted to maintain control over those phases of alcoholic beverage traffic that could not be effectively controlled by the states.<sup>5</sup> Thus, the Federal Alcohol Control Administration (FACA) was established during the 1933 Congressional recess by an executive order issued under the National Industrial Recovery Act (NIRA).<sup>6</sup> One of this agency's primary purposes was to protect the consumer against deception from false and misleading labeling and advertising of alcoholic beverages where mislabeling was defined as the use of labels which were not in compliance with the Food and Drug Act.<sup>7</sup>

After the NIRA was declared unconstitutional in 1935, Congress immediately passed the Federal Alcohol Administration Act (FAAA) which created the Federal Alcohol Administration (FAA) within the Department of the Treasury.<sup>8</sup> The FAAA created a permit system which required that all alcohol labels be approved by the FAA. FAAA §205(e) also gave the FAA the discretion to require that labels furnish consumers with information that would advise them of the identity, quality, and net contents of alcoholic beverages. The legislative history of the

Hancock, Mary, *Federal Jurisdictional Disputes in the Labeling and Advertising of Malt Beverages*, 34 Food Drug Cosmetic Law Journal 271, 272 (1979).

<sup>6</sup> Exec. Order No. 6474 (Dec. 4, 1933).

Cooper, Iver P., *The FDA, the BA TF, and Liquor Labeling: A Case Study of Interagency Conflict*, 34 Food Drug Cosmetic Law Journal 370, 372 (1979).

<sup>7</sup> 49 Stat. 977 (1935). This agency was absorbed into the Alcohol Tax Unit of the Bureau of Internal Revenue in 1940 and was later spun off as the ATF under the Department of the Treasury in 1972.

FAAA indicates that this provision was not meant to just prohibit false statements but was also intended to ensure that consumers would be provided with all the important factors which were of interest [to them] about what was in the bottle.<sup>9</sup>

The regulations issued by the FAA did not require ingredient labeling on alcoholic beverages but did prohibit, among other things, statements that were indicative of curative or therapeutic effects if they were either untrue or would tend to create a misleading impression in the minds of consumers.<sup>10</sup> Thus, it is clear that while the FAAA went much further in positive demands upon producers [to] advise the public of the nature of their products than any earlier legislation with respect to liquor or any other product not actually dangerous, the FAA never did exercise that full authority. Curiously, therefore, neither the FDA nor the FAA exercised the full measure of their regulatory jurisdiction over alcoholic beverage labeling.

The first attempt to reconcile the overlapping jurisdictional grants of the FDA and the FAA occurred shortly after the abolishment of the FAA by the Reorganization Act of 1939. This action transferred the s duties to the Alcohol Tax Unit of the Bureau of Internal Revenue. On April 11, 1940, the FDA stated that while it had concurrent jurisdiction over alcohol labeling it was adopting a policy of deferral to the Alcohol Tax Unit in order to avoid duplication of effort. This was formalized in a Trade Correspondence as follows:

Statement of Joseph H. Choate, Jr., *Hearings on HR. 8539 Before the Committee on Ways and Means*, 74th Cong., 1st Sess. (1935), at 10.

<sup>10</sup> 27 CFR §7.29.

~ Russell, T., *Controls over Labeling and Advertising of Alcoholic Beverages*, 7 Law & Contemp. Prob. 645, 649 (1940).

While we have indicated that cordials, liquors, wine and whisky [and beer] are subject to the Act [of 1938], we will continue as in the past to leave [regulation of] labeling of these alcoholic beverages under the more specific Federal Alcohol Administration Act.<sup>12</sup>

This policy of deferral by the FDA was destined not to last, however.

Two events in particular illustrate that the jurisdictional lines were not clearly defined nor

respected after this memorandum of understanding. First, after a flood in Missouri washed labels off of bottles in several breweries and distilleries in 1954, the FDA took legal action to seize the bottles for violations of the misbranding provisions of the 1938 FDCA.<sup>13</sup> Then in 1962, the Alcohol and Tax Unit told distillery owners that the issuance of certificates of label approval under the Federal Alcohol Administration Act .. .does not waive their responsibilities to observe the laws and regulations administered by the Food and Drug Administration.<sup>14</sup> Thus, clearly both agencies still felt that the FDA had some jurisdiction over alcoholic beverage labeling.

The next attempt to resolve the jurisdictional overlap was spurred by the 1972 effort by the Center for Science in the Public Interest (CSPI) to force the government to mandate ingredient labeling on all alcoholic beverages. CSPI's efforts were motivated by two specific events. The first was a 1964 incident in which 47 people in Canada and the U.S. died from cobalt poisoning resulting from the interaction between by the cobalt sulfate used as a foam stabilizer in beer and the alcohol contained in the beer. The second motivating event was the 1971 discovery by Swedish scientists that the preservative diethylpyrocarbonate (DEPC), used in

<sup>12</sup> Trade Correspondence No. 224 (April 11, 1940).

*United States v. 1,800.2625 Wine Gallons of Distilled Spirits*, 121 F.Supp. 735 (D.C. W.D. Mo. 1954). <sup>14</sup> Industry Circular No. 62-33 (Oct. 26, 1962).

both beer and wine, reacted with the ammonia contained in these beverages to form the carcinogen urethan. As a result of these events, CSPI petitioned FDA to enforce the FDCA ingredient labeling provisions and also petitioned the ATF to exercise its discretion under the FAAA to declare the withholding of ingredient information on alcoholic beverages misleading.

The FDA deferred to the ATF in this matter after the ATF agreed to issue ingredient labeling regulations. This deferral was formalized in another memorandum of understanding in which the ATF was designated as the agency with primary responsibility for promulgating alcohol beverage labeling regulations pursuant to the FAAA as long as those regulations were also consistent with the food labeling requirements of the Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.<sup>15</sup> One analysis of the language of this memorandum of understanding has led to the conclusion that it did not involve a subdelegation of the FDA's regulatory authority to the ATF and therefore the ATF's regulatory jurisdiction is still based on FAAA §205 rather than FDCA §343.<sup>16</sup>

The ATF did propose ingredient labeling regulations based largely on a voluntary proposal by the Brewers' Association of America.<sup>17</sup> However, on November 11, 1975, the ATF withdrew these proposals based upon several claims the most believable of which were that the cost of ingredient labeling would exceed the benefits to consumers and that aging would change

<sup>15</sup> 39 F.R. 32617 (Oct. 8, 1974).

<sup>16</sup>

Cooper, *supra* note 7, at 382. Although Cooper states that statutory authorization is necessary for joint rule making and admits that this does not exist with respect to the FDA and the ATF, he still calls for the ATF to include the FDA in an Interagency Committee on Federal Activities for Alcohol Abuse and Alcoholism and cites the cooperation between the FDA and the FTC as a model for the FDA and the ATF. *Id.*, at 384.

<sup>17</sup> 39 F.R. 27812 (Aug. 1, 1974).



the contents of alcoholic beverages in such a way that labels would be inaccurate and possibly misleading.<sup>18</sup> Two weeks after the ATF withdrew its proposed regulations, the FDA revoked its 1974 memorandum of understanding and announced that it would begin to enforce its own requirements for the ingredient labeling of alcoholic beverages by January 1, 1977.

Thus, on May 5, 1976, the FDA issued a booklet illustrating proposed alcoholic beverage labels.<sup>19</sup> The relationship between the FDA and the ATF at this point was still far from strained, however. On June 16, 1976, officials of both the FDA and the ATF met to discuss the labeling issue. At this meeting, FDA Commissioner Schmidt stated that the FDA would be willing to enter into another memorandum of understanding in which the FDA would accept current ATF approved labels as being in compliance with the FDCA for all aspects of alcoholic beverages except for ingredient labeling. Commissioner Schmidt also stated that the FDA was willing to work together with the ATF to develop regulations which would satisfy the requirements of FDCA §343.<sup>20</sup> This attempt at reconciliation did not succeed, however, and the next stage of the relationship between the two agencies occurred in the courts.

#### B. Court Involvement

The alcoholic beverage industry had a mixed reaction to the dialogue between the FDA and the ATF on the issue of ingredient labeling. While the U.S. Brewers' Association was willing to work with the FDA, representatives of the distilled spirits and wine industries brought

<sup>18</sup> 40 F.R. 52613 (Nov. 11, 1975).

<sup>19</sup> 41 F.R. 18538 (May 5, 1976).

<sup>20</sup> Cooper, *supra* note 7, at 376.

suit seeking a declaratory judgement that the FDA had no authority to regulate the labeling of alcoholic beverages. This suit was strategically brought in the Western District Court of Kentucky which was the heart of the whisky country. In November 1976, this court held that the ATF had exclusive jurisdiction to regulate the labeling of alcoholic beverages because Congress had intended FAAA §205 to govern alcoholic beverage labeling to the exclusion of FDCA §343. The court stated that this conclusion was supported by the fact that there was a history of deferral by the FDA to the ATF.<sup>21</sup> It has been argued that this decision was incorrect and that by denying the FDA concurrent jurisdiction over alcohol labeling along with the ATF, the court effectively denied the expression of Congressional will as embodied in the FDCA.<sup>22</sup>

The FDA wanted to appeal this decision but on July 20, 1977, the Office of Management and Budget (OMB) stepped in and decided that it should not be appealed because the ATF could most efficiently and effectively administer alcoholic beverage regulations. OMB did recognize, however, that the FDA's stated concerns about the right of consumers to be informed of hidden or potentially harmful ingredients in alcoholic beverages were valid. Thus, the OMB ruled that the FDA and the ATF should work together to develop partial ingredient labels and that special focus should be placed on assuring that consumers are made aware of hidden and potentially harmful ingredients...and on reducing the economic burden on manufacturers of providing such data.<sup>23</sup> This was not the end, however, of court involvement in the labeling saga.

*Brown-Forman Distillers Corp v. Mathews*, 435 F. Supp. S (W.D. D.C. Ky. 1976), at 16. 22 Cooper, *supra* note 7, at 389.

23 Hancock, *supra* note 5, at 280.

In response to the OMB decision, the ATF issued a final rule containing ingredient labeling regulations for all alcoholic beverages.<sup>24</sup> These regulations, which were to become mandatory on January 1, 1983, required the disclosure of ingredients used in the production of alcoholic beverages either by placing an ingredient list directly on the alcoholic beverage label or by providing a U.S. mailing address on the label where such ingredient information would be made available. The regulations also required producers to disclose the presence of FD&C Yellow No. 5 because this additive had been determined to be a potentially harmful allergen by the FDA.

In response to President Reagan's Executive Order 12291 which directed government agencies to conduct cost-benefit analyses of all existing regulations, the ATF decided to rescind its ingredient labeling rule.<sup>25</sup> The ATF based this decision on the conclusion that the labeling regulations would increase costs to consumers and burdens on industry which are not commensurate with the benefits that might flow from the additional label information and would not result in an appreciable benefit to consumers when compared to the existing label information requirements and standards of identity.<sup>26</sup> Thus, the ATF abandoned its labeling regulations before they even took effect.

After this action, CSPI brought suit in the Federal District Court in Washington, D.C. claiming that the ATF's rescision violated the FAAA and the Administrative Procedure Act

<sup>24</sup> ~ FR. 40538 (June 13, 1980).

<sup>25</sup> 46 F.R. 55093 (November 6, 1981).

<sup>26</sup>

*Id.*, at 55094.

(APA). The court held that FAAA §205 did express a Congressional intent to provide the ATF with the discretion to issue regulations which it felt would provide consumers with information about the quality and identity of alcoholic beverages.<sup>27</sup> However, the court held that because the FAAA did not condition such a grant of authority with a proviso that the regulations could be withdrawn if the costs to the industry turned out to be too high, the ATF's action violated the

FAAA.<sup>28</sup>

The court further held that because the ATF did not consider the costs of the address label option in its decision to rescind the regulations, it had acted in an arbitrary and capricious manner that violated the APA.<sup>29</sup> Finally, the court held that the existing label information and standards of identity would not sufficiently protect consumer interests. The court noted that standards only existed for wine and distilled spirits and not malt beverages and that it was clear from the FD&C Yellow No. 5 incident that the ATF's maintenance of standards of identity had not been sufficient to protect consumers because there was no automatic linkage between the FDA's regulation of food labels and the ATF's regulation of alcoholic beverage labels.<sup>30</sup>

Although the ATF appealed this decision, it did reinstate the labeling regulations.<sup>31</sup> During the period of time in which the appeal arguments were being heard, the ATF conducted

<sup>27</sup> *Center for Science in the Public Interest, et al., v Department of the Treasury, et al.*, 573 F.Supp 1168 (D.C. D.C., February 9, 1983).

<sup>28</sup> *Id.*, at 1174.

<sup>29</sup> *Id.*, at 1176.

<sup>30</sup> *Id.*, at 1177.

<sup>31</sup> 48 FR. 10309 (March 11, 1983).

another review of its labeling regulations. Once again it concluded that the costs of providing full ingredient information to consumers outweighed the benefits and rescinded the regulations. This second rescision was justified by the ATF on the grounds that consumers had not revealed an overwhelming desire for full ingredient disclosure, the transformation of alcoholic beverage ingredients after production made it impossible to label accurately, the cost of the address label option was nearly as burdensome as full ingredient labeling, and FD&C Yellow No. 5 could be labeled individually. However, BATF did impose a requirement mandating disclosure of the use of FD&C Yellow No. 5 in any alcoholic beverage by October 6, 1984.<sup>32</sup>

Given the ATF's second rescision of its labeling regulations, the Court of Appeals hearing the appeal dismissed all claims without prejudice so that a new trial could begin based upon the ATF's new rationale in the second rescision.<sup>33</sup> Thus, CSPI filed a new suit in the district court and the cycle began once again. Again, the district court held that the ATF's rescision of its ingredient labeling regulation violated the FAAA and the APA.<sup>34</sup> The court based its decision on the conclusion that the ATF used basically the same rationale as in the prior rescision so that the latest rescision merely represents a predetermined 'mind set' to reinstate a previous position which was held unlawful.<sup>35</sup>

The ATF again appealed the district court's decision and this time the appeals court did

32 48 FR. 45549 (October 6, 1983).

*Center for Science in the Public Interest, et al., v Donald T. Regan, Secretary of the Treasury, et al.*, 726 F.2d 1161 (D.C. D.C. Cir, February 7, 1984).

~ *Center for Science in the Public Interest et al., v Department of the Treasury, et al.*, 1985 U.S. Dist. LEXIS 14329 (D.C. D.C., October 30, 1985).

~ *Id.*, at 15.

hear the case. The appeals court reversed the district court decision.<sup>36</sup> The court rejected the ATF's conclusion that there was a lack of consumer interest in ingredient disclosure but did agree that because both basic ingredients and additives will be substantially transformed by distillation and fermentation ingredient labeling would largely be useless to consumers.<sup>37</sup> Thus, the court held that the ATF's recision was based on a justifiable and reasoned analysis and did not violate either the FAAA or the APA. The court also approved the ATF's case by case approach to health effects of specific ingredients and its requirement of labeling for the presence of FD&C Yellow No. 5.<sup>38</sup> This decision marked the end of nearly a decade of court battles over the ATF ingredient labeling policy.

#### C. Subsequent Action and Current Relationship

The complex relationship between the FDA and the ATF evident in both the executive and judicial branch actions described above highlights two important points. First, it is clear that there was never a clear delineation of the jurisdictional grounds occupied by the FDA and the ATF. While the FDA did generally defer to the ATF, there were cases in which the FDA did attempt to assert its legislatively mandated authority. Second, it is clear that the ATF actually deferred to the FDA, or at least relied on the FDA, in certain instances despite the fact that it had been granted sole jurisdiction by the courts. For example, the ATF relied on the FDA's regulation of food additives in determining that the presence of FD&C Yellow No. 5 should be

<sup>36</sup> *Center for Science in the Public Interest, et al., v Department of the Treasury, et al.*, 797 F.2d 995 (D.C. Cir. August 5, 1986).

<sup>37</sup> *Id.*, at 1000.

<sup>38</sup> *Id.*, at 1002.

disclosed on alcoholic beverage labels. Thus, there was a need for the FDA and the ATF to establish a more structured and detailed relationship after the final appeals court decision not only to prevent future conflicts but also to prevent regulatory overlap and duplicity.

The agencies did just this in a de facto way through their interaction with regard to the labeling of sulfites in the food supply. The development of the sulfite labeling policy illustrates a deliberate attempt by the FDA and the ATF to develop a clear working relationship. The FDA had first issued a proposed rule to affirm the generally recognized as safe status of sulfites on July 9, 1982.<sup>40</sup> While the FDA was conducting its study of sulfites, the ATF proposed a rule to require reductions of permitted levels of sulfites in wine to 275 parts per million.<sup>40</sup> In the preamble to this proposed rule, the ATF stated that if at some future date the U.S. Food and Drug Administration were to determine that the sulfiting of foods and beverages presents a risk to public health and requires labeling disclosure, ATF [will] promptly propose disclosure in labeling of sulfur dioxide and sulfiting agents.<sup>41</sup> Thus, the ATF was clearly willing to defer to the scientific determinations of the FDA as long as it retained control over the final form of the labeling regulations.

The FDA issued its final ruling requiring the declaration of the presence of sulfites at levels greater than 10 ppm on food labels on July 9, 1986.<sup>42</sup> In this ruling, the FDA noted that a wine industry trade association had submitted a comment to its proposed sulfite labeling rule

<sup>40</sup> 47 F.R. 29956 (July 9, 1982). <sup>40</sup> 49 F.R. 37527 (September 24, 1984).

<sup>41</sup> *Id.*

<sup>42</sup> 51 F.R. 25012 (July 9, 1986).

even though the labeling of wines is regulated by the ATF. The FDA stated that the issues raised in the comment relate directly to wine and have no bearing on the action that FDA is taking and thus refused to respond to the comment. This action shows that the FDA was highly aware of the need to clearly delineate lines of jurisdiction with the ATF and wished to defer to the ATF on the actual form of, and requirements for, alcoholic beverage labeling.

The ATF did issue its own final rule on sulfite labeling on September 30, 1986.<sup>44</sup> In this ruling, the ATF confirmed that it was deferring to the scientific analysis of the FDA stating that since FDA has determined that the presence of undeclared sulfites in foods and beverages poses a recognized health problem to a certain class of individuals, ATF believes that the declaration of sulfites in the labeling of alcoholic beverages is necessary.<sup>44</sup> The ATF also staked out its own jurisdictional territory, however, by permitting a label declaration which read contains sulfites rather than requiring a listing of the specific sulfiting agent as the FDA rule had done. The ATF also permitted the use of a neck label containing the sulfite declaration in place of a statement printed on the label itself. Thus, it was clear that while the ATF did agree to defer to the FDA's scientific analysis, it desired to retain control over the form of alcohol labeling.

This new relationship between the FDA and the ATF was formalized in a November 30, 1987 memorandum of understanding.<sup>45</sup> The stated purpose of this memorandum was to clarify and to delineate the enforcement responsibilities of each agency with respect to alcoholic

~ 51 F.R. 34706 (September 30, 1986).

~ *Id*

~ 52 FR. 45502 (November 30, 1987).



beverages considered adulterated under the Federal Food, Drug, and Cosmetic Act of 1938 and for other related purposes.<sup>46</sup> Thus, the memorandum focused on the jurisdictional overlap between the FDA's authority to prevent adulteration in the food supply under the FDCA and the ATF's more general broadly worded mandate under the FAAA. In this memorandum, the AIF agreed to promulgate labeling regulations when FDA has determined that the presence of an ingredient in food products, including alcoholic beverages, poses a recognized public health problem.<sup>47</sup> The ATF and the FDA also agreed to consult on a regular basis concerning the propriety of promulgating regulations concerning the labeling of other ingredients and substances for alcoholic beverages with the FDA agreeing in particular to upon ATF's request, provide ATF with a health hazard evaluation with respect to any substance found in alcoholic beverages.<sup>48</sup>

This new inter-agency relationship was confirmed by subsequent regulations relating to sulfites and aspartame. In 1988, the FDA revisited the GRAS level of sulfites in the food supply and determined that those who drink wine or beer regularly would not be exposed to more than 180 milligrams of additional sulfur dioxide per day.<sup>49</sup> The FDA based this estimate on the proposed limitation on sulfite levels in beer and wine contained in the ATF's 1984 proposed rule. However, it is evident that the ATF's proposal was motivated by the FDA's initial study of the GRAS level of sulfites. Thus, this shows that the FDA will take the lead in the scientific

<sup>46</sup> *Id.*

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*Id*

<sup>48</sup> *Id*

<sup>49</sup> 53 FR. 51065 (December 19, 1988).

research necessary to establish the safety and health effects of alcoholic beverages and that the ATF will use this research in developing its labeling regulations.

The ATF's acceptance of this understanding was confirmed by its final rule on materials and processes authorized for the production of wine of October 7, 1993 ~ In this ruling, the ATF stated that it had never promulgated a final ruling to lower the permitted levels of sulfites in the production of wine after its 1984 proposed rule because of the proposal by the Food and Drug Administration to lower the maximum level of sulfiting agents in wine from 350 parts per million to 275 ppm and the fact that AFT was still awaiting final action by FDA before proceeding further in this area.,<sup>51</sup> Thus, the ATF confirmed that while it has the jurisdiction to set the maximum level of sulfites in alcoholic beverages it is going to defer to the FDA's determinations of the GRAS level before it does so. This shows a clear intent by the ATF to defer to the FDA's scientific determinations as outlined in the third memorandum of understanding.

The ATF explicitly stated that this is its policy in a final rule requiring the disclosure of aspartame in the labeling of malt beverages.<sup>52</sup> In this ruling, the ATF stated that in determining whether there is a need to require label disclosure of specific ingredients in alcoholic beverages, ATF has traditionally utilized the expertise of the Food and Drug Administration and that the memorandum of understanding had formalized this policy.<sup>53</sup> Thus, both agencies now agree that

~ 58 FR. 52222 (October 7, 1993).

~ *Id.*, at 52223.

<sup>52</sup> 58 F.R. 44131 (August 19, 1993).

~ *Id.*

the FDA is responsible for considering and evaluating the scientific evidence related to the health and safety effects of alcoholic beverages and that the ATF will follow the FDA's lead in promulgating labeling requirements related to them. Even though this is an area of concurrent regulatory jurisdiction, it appears that the two agencies have finally made their peace and established a working relationship that is designed to prevent future conflict and confusion. As will be discussed below, the nature of this relationship may have important implications for the possibility of adding a health claim to wine labels.

## Section II. Health Claims on Wine Labels

Given the reliance by the ATF on the scientific analysis of the FDA in alcoholic beverage labeling regulation for health and safety concerns, it seems logical for the ATF to also rely on the FDA's scientific analysis for the regulation of health claims. Thus, it is useful to analyze the FDA regulation of health claims on food products in order to explore the possibility of a health claim on wine labels noting the connection between the moderate consumption of wine and reduced risks of coronary heart disease (CHD). Such an analysis, however, must contend not only with the jurisdictional overlap of the FDA and the ATF but also the 1990 Congressional amendment of the FDCA to include specific provisions governing the regulation of health claims on food products<sup>54</sup> and the more recent 1997 Food and Drug Modernization Act (FDMA) provisions streamlining the health claims approval process.<sup>55</sup> The regulatory action of the FDA under the 1990 amendments will be analyzed in the first section below. The second will then

- ~ FDCA §403(r)(3).
- ~ Ill Stat. 2296 (1997).

discuss the relevance of the FDA and the ATF jurisdictional overlap. Finally, the third section will apply the FDA regulatory policy and the FDMA provisions to the consideration of a wine health claim.

**A. FDA Regulatory Policy Under the 1990 FDCA Amendments**

In the 1990 FDCA amendments, Congress directed the FDA to study 10 specific disease/nutrient relationships for possible health claims. Based upon its analysis of these 10, the FDA eventually approved eight health claims for use on food labels.<sup>56</sup> The FDA's action on the health claim relating 'diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products containing fiber (particularly soluble fiber) to reduced risks of coronary heart disease' is representative of the agency's method of analysis of these 10 health claims. Since the study of these original 10 relationships, the FDA has considered and approved several health claims for disease/nutrient relationships that are either related to, or are subsets of, the original

10. Among these is a health claim relating 'diets high in soluble fiber from whole oats to reduced risks of coronary heart disease'. An analysis of the FDA's action with respect to both the general dietary fiber and the whole oats claims are particularly useful for considering the possibility of a wine health claim.

The 1990 Congressional amendment of the FDCA had actually directed the FDA to examine the relationship between the consumption of general dietary fiber and coronary vascular disease (CVD) instead of CHD. However, when the FDA made its first proposed rule permitting

<sup>56</sup> These are calcium and osteoporosis (58 F.R. 2665), dietary lipids and cancer (58 F.R. 2787), sodium and hypertension (58 F.R. 2820), dietary saturated fat and cholesterol and risk of coronary heart disease (58 FR 2739), fiber-containing grain products, fruits, and vegetables and cancer (58 FR. 2537), fruit, vegetables, and grain products that contain fiber (particularly soluble fiber) and risk of coronary heart disease (58 F.R. 2552), fruits and vegetables and cancer (58 F.R. 2622), and folate and neural tube defects (58 F.R. 53254).

such a health claim, it restricted the claim to the connection between general dietary fiber and CHD rather than the broader CVD because this link had the strongest scientific support.<sup>57</sup> In the final regulation permitting the health claim, the FDA also stated that while there was evidence of a link between the consumption of specific types of soluble fiber, such as oat fiber, and reduced risks of CHD, the various fiber sources also appear to have different mechanisms of action and different relative magnitudes of effect thus suggesting that caution is necessary before generalizing from one type of dietary fiber to another.<sup>58</sup> Therefore, the FDA restricted the health claim to general dietary fiber from fruits, vegetables, and grain products rather than allowing the claim to cover all types of dietary fiber which would include oat fiber.

These two actions show that the FDA has taken a very cautious and scientifically grounded approach to the analysis of health claims. Rather than seeking to expand the scope of any health claim, the FDA has sought to tailor claims as narrowly as possible so that they stand on the greatest scientific support. This approach accords with the 1990 FDCA amendments which direct the FDA to approve a health claim only when the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) [shows] that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported.<sup>59</sup>

<sup>57</sup> 56 F.R. 60582 (November 21, 1991).

<sup>58</sup>

<sup>59</sup> 58 F.R. 2552 (January 6, 1993), at 2561.

It is also important to note that the FDA required that the general dietary fiber health claim be made in the context of a diet low in saturated fat and cholesterol. Comments to the FDA's proposed rule had stated that this requirement implicitly rejected authoritative government reports such as National Cholesterol Education Program (NCEP) pamphlets which connected the consumption of soluble dietary fiber alone to reduced cholesterol levels and thus reduced risks of heart disease. In response to this criticism, the FDA stated that these comments distorted the government reports by failing to acknowledge important contributions to reduced risk of disease by the wide variety of nutrients and non-nutritive substances present in diets high in fruits, vegetables, and grain products and by ignoring the fact that the NCEP pamphlets also recommended a habitual pattern of eating that is consistently low in saturated fatty acids, total fat, and cholesterol.<sup>60</sup>

Thus, the FDA concluded that the statement that 'diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber (particularly soluble fiber) are related to a reduced risk of coronary heart disease' was most consistent with the available scientific evidence and did not contradict official government statements.<sup>61</sup> Furthermore, the FDA stated that the general dietary fiber health claim could state that such diets were consistent with the U.S. Dietary Guidelines published by the U.S. Department of Agriculture and the Department of Health and Human 62 Thus, it is clear that the FDA

<sup>60</sup> 58 F.R. 2552, at 2564.

<sup>61</sup> *Id.*, at 2572.

<sup>62</sup>

*Id.*, at 2574.

may require that health claims be placed within the context of an overall diet that accords with other official government recommendations before it will sanction a specific health claim.

At the same time that the FDA published its final decisions with respect to the original 10 nutrient/disease relationships, it also published general regulations for all future health claims.<sup>63</sup> Among these regulations, was a requirement that any food making a health claim have 10 percent or more of the Daily Reference Value (DRV) for Vitamin A, Vitamin C, iron, calcium, protein, or fiber per serving *prior* to nutrient fortification.<sup>64</sup> The FDA quickly recognized, however, that this requirement would prevent food products that have been specially formulated relative to a specific disease condition (e.g. sugarless gum and cavities) but which have limited nutritional value from making health claims.<sup>65</sup> Thus, the FDA modified its regulations to state that the 10 percent requirement would only apply if it had not been specifically waived by regulation.

The FDA soon used this exemption possibility to modify the health claim for general dietary fiber and CHD.<sup>66</sup> In this ruling, the FDA noted that it was concerned that health claims are not being used as extensively as they could be, despite the fact that many foods qualify for such claims. The FDA stated that the National Food Processors Association (NFPA) had alleged that the 10 percent requirement arbitrarily prohibited some common fruits, vegetables, and other wholesome and nutritious food from making health claims related to CHD and that it

<sup>63</sup> 58 F.R. 2478 (January 6, 1993); 21 CFR § 100, et seq.

<sup>64</sup> 21 CFR 101.14(e)(6), *emphasis added*.

<sup>65</sup> 58 F.R. 44036 (August 18, 1993).

<sup>66</sup>

60 F.R. 66206 (December 21, 1995).

was modifying its dietary fiber health claim to rectify this situation.<sup>67</sup>

Then the FDA proposed that fruit and vegetable products comprised solely of fruits and vegetables, enriched grain products that conform to a standard of identity, and bread that conforms to the standard of identity for enriched bread except that it contains whole wheat or other grain products not permitted under that standard, that do not meet the 10 percent nutrient contribution requirement, but that meet all other aspects of the health claim, should be permitted to bear a health claim.<sup>68</sup> The FDA stated that it would limit this exception to those food products composed solely of whole fruits and vegetables, and those grain based food products which conformed to a standard of identity, so that food products which may raise the level of certain other nutrients, such as fat, cholesterol, and sodium would not be able to make the health claim. The FDA reasoned that otherwise there would be a potential for health claims which would be inconsistent with the purpose of the health claim and incompatible with current dietary guidelines.<sup>69</sup>

This action demonstrates that the FDA will use the regulatory flexibility which was built into the health claims approval process in order to broaden the range of foods allowed to make health claims when it feels that doing so is beneficial to the general health of the American public. Most notably, the FDA's idea of what is beneficial to the health of the general public seems to be driven by those disease/food relationships for which there is strong scientific support *and* those foods which meet the standards of a healthy diet as defined by the U.S. Dietary

at 66211.

<sup>68</sup> *Id.*, at 66213.

<sup>69</sup>

*Id.*



Guidelines. Thus, the FDA seems to conceive of the purpose of health claim regulation as reinforce[ing] the Surgeon General's recommendations and help[ing] Americans to maintain a balanced and healthful diet.<sup>70</sup>

The FDA's action approving a health claim noting the connection between the consumption of oat bran and reduced risks of CHD illustrates further nuances in its regulatory policy. First, the FDA agreed to permit a shortened health claim which merely noted the existence of a relationship 'between diets high in oat bran and oatmeal and reduced risk of heart disease' as long as there was a statement referring consumers to the location of the full health claim that placed this statement within the context of a diet low in saturated fat and cholesterol.<sup>71</sup> The FDA allowed the abbreviated claim at the request of industry and because it felt that the dietary message could be effectively communicated by including a statement referring to the location of the full claim. However, the FDA did note that it did not intend for the abbreviated message to suggest to consumers that adding oats to the diet was the only dietary modification necessary to help them reduce risk of CHD.<sup>72</sup> Thus, the FDA was concerned with preventing the public from perceiving that oats and oatmeal were magic bullets for reducing CHD.

Second, the FDA did not mandate specific language for the claim but instead provided a model claim which included the word 'may.' For example, in a subsequent ruling on health claims for all forms of soluble fiber, FDA provided a sample oat bran claim which read soluble

<sup>70</sup> *Id.*, at 66208, *quoting*, House Committee on Energy and Commerce, *Nutrition Labeling and Education Act of 1990*, 101st Congress, 2d Sess., Report 101-538 (June 13, 1990), at 9-10.

<sup>71</sup> 62 F.R. 3584 (January 23, 1997).

<sup>72</sup> *Id.*, at 3594.

fiber from foods such as oat bran in Brand Name Cereal, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.<sup>73</sup> The FDA stated that it approved the use of the word 'may' because it agreed with industry that using 'may' to relate the ability of oat bran or oatmeal to reduce the risk of heart disease is intended to reflect the multifactorial nature of the disease.<sup>74</sup> This shows that while the FDA did not want to mislead the public about the benefits of oat bran, it was willing to tolerate a claim which contained words conveying shades of meaning.

Third, the FDA required that any food making a health claim for oat bran contain at least .75 g per serving even though there was no DRV for soluble fiber.<sup>75</sup> This was a departure from the previous policy under which the FDA had used the definition of what constituted a product that was 'high in' a particular nutrient as the minimum qualifying level for allowing a health claim. The FDA did note in a subsequent ruling on health claims for psyllium fiber that it does intend to establish a DRV for soluble fiber, and, once that rule making is completed, assuming it results in a DRV, [it will] revisit the requirements of the oat bran minimum qualifying level.<sup>76</sup> However, this shows that the FDA is willing to approve a health claim even without a definitive standard for the appropriate level of consumption of a food in the generally recommended daily diet.

Finally, even though the FDA's analysis of the benefits of oat bran and oatmeal was

~ 62 F.R. 15343 (March 31, 1997).

~ 62 F.R. 3584.

~ *Id.*, at 3592.

76 62 F.R. 28234 (May 22, 1997), at 28241.

based on the presence of b-glucan soluble fiber in oats, it stated that it is premature to authorize a broader claim for soluble fiber from certain foods based merely on the present of b-glucan in those foods. Instead, the FDA will require documented proof of the health benefits from the consumption of any specific food, even if those benefits are derived from b-glucan-like soluble fiber, before it will approve a health claim for that food.<sup>77</sup> Thus, although the FDA exhibited a great deal of flexibility with respect to its approval of a health claim for oat bran it still stuck to its rigorous scientific standards by refusing to allow other food products containing soluble fiber to piggyback on oat bran's health claim. The FDA demonstrated its commitment to this policy in its approval of a health claim for soluble fiber from psyllium husks, which is similar to bglucan soluble fiber from whole oats, and reduced risks of CHD by requiring separate scientific proof of a connection between the consumption of psyllium and reduced risks of CHD.<sup>78</sup>

#### **H. Relevance of the FDA and the ATF Jurisdictional Overlap**

Before automatically applying the FDA method of analysis of health claims for food to health claims for wine, it is necessary to consider the impact of the jurisdictional overlap between the FDA and the ATF with respect to alcoholic beverage labeling. On their face, the *BrownForman* decision and the language of the FAAA indicate that the ATF has exclusive jurisdiction over all alcoholic beverage labeling. This would mean that the ATF would also have exclusive jurisdiction over the regulation of health claims on alcoholic beverage labels. Indeed, the ATF regulations promulgated under the FAAA do address this issue to some degree. The ATF

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62 F.R. 3584, at 3587. 78 62 F.R. 28234 (May 22, 1997).

regulations state that:

Labels shall not contain any statement, design, representation, pictorial representation, or device representing that the use of [alcoholic beverages] has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression.<sup>79</sup>

Because this regulation does not prohibit health claims, however, it would seem that non-misleading health claims would be permitted.

Despite this regulation, the ATF has never permitted a health claim on alcoholic beverages. In an industry circular published in response to inquiries about the possibility of health claims, the ATF did acknowledge that there is a growing body of scientific research and other data that seems to provide evidence that lower levels of drinking decrease the risk of death from coronary artery disease.<sup>80</sup> The ATF stated in this circular that it intended to engage in rule making and that pending the initiation of rule making proceedings, ATF will continue to evaluate health claims made in the labeling and advertising of alcoholic beverages on a case-by-case basis.<sup>81</sup> Nevertheless, the ATF expressly discouraged any attempts to obtain case-by-case approval by declaring that any health claim would have to be voluminously qualified and that it considers it extremely unlikely that such a balanced claim would fit on a normal alcoholic beverage label.<sup>82</sup>

In response to the lack of action by the ATF, the Competitive Enterprise Institute (CEI)

27 CFR §4.39(h); 5.42(b)(8); 7.29(e).

<sup>80</sup>

*Health Claim in the Labeling and Advertising of Alcoholic Beverages*, BATF Industry Circular No.

IC-93-8 (August 8, 1993).

<sup>81</sup> *Id*

<sup>82</sup>

petitioned the ATF on May 9, 1995 to adopt a rule allowing the use of the statement that 'There is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of heart disease' on all alcoholic beverage labels.<sup>83</sup> The ATF acknowledged the receipt of CEI's petition but took no further action. When Consumer Alert (CA), another consumer advocacy group, sent the ATF a letter of support for CEI's petition, the ATF responded with a letter stating that it believed that such health statements would likely be misleading and that it still did intend to engage in rule making on the issue.<sup>84</sup> In response to the ATF's inaction, CEI and CA filed suit against the ATF on October 29, 1996.

The CEI/CA lawsuit contains three allegations. First, CEI/CA allege that the ATF's action violated the First Amendment because its refusal to approve labels containing a health claim violated the rights of speakers (i.e. producers and sellers of alcoholic beverages) and listeners (i.e. consumers) to receive truthful, non-misleading information.<sup>85</sup> The suit also alleges that the ATF's action violates the FAAA and regulation 4.3 9(h) promulgated thereunder. Finally, the suit alleges that the ATF's failure to respond to CEI's petition in a timely manner violates the Administrative Procedure Act.

In support of its position, CEI/CA noted that more than 100 studies conducted over the previous decade have concluded that moderate drinking reduces the risk of contracting

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*Competitive Enterprise Institute and Consumer Alert v. Robert E. Rubin, in his official capacity as Secretary of the United States Department of the Treasury, and John W. Magaw, in his official capacity as Director of the Bureau of Alcohol, Tobacco, and Firearms*, Complaint filed with the U.S. District Court for the District of Columbia, at 7.

<sup>84</sup> *Id*

<sup>85</sup> *Id*, at 10.

cardiovascular disease and reduces overall mortality.<sup>86</sup> CEI/CA also cited a 1992 New England Journal of Medicine literature review which stated that 'there is a substantial body of observational epidemiologic evidence to suggest that moderate consumption of alcohol reduces the risk of heart disease.'<sup>87</sup> Finally, CEI/CA noted that the health benefits of moderate drinking were officially recognized by the U.S. Government in the form of the U.S. Dietary Guidelines which state that current evidence suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals.<sup>88</sup> As of the time of this writing, this suit has not yet been resolved.

Given the ATF's intransigence in approving health claims for alcoholic beverages, it is useful to consider whether a case can be made for FDA jurisdiction over the issue. The third memorandum of understanding between the FDA and the ATF may be particularly relevant. As noted above, this memorandum delineated a clear working relationship between the two agencies with respect to health and safety labeling of alcoholic beverages under which the ATF would defer to the FDA's scientific determinations. As the regulatory action taken with respect to sulfites and aspartame showed, the ATF has explicitly relied on the FDA's scientific determinations in regulating the content of alcoholic beverage labels. Thus, it may be logical for the ATF to rely on the FDA's analysis with respect to health claims for alcoholic beverages also. After all, the FDA's regulation of health claims is clearly grounded in the same sorts of scientific

<sup>86</sup> *Id.*, at 4.

<sup>87</sup> *Id.*, at 5, *citing*, Manson, et al, *The Primary Prevention of Myocardial Infarction*, 326 New England Journal of Medicine 1406 (1992), at 1412.

<sup>88</sup>

USDA and HHS, Dietary Guidelines for Americans (4th ed., Dec. 1995), at 40.

evaluations required in health and safety regulation.

There is precedent for proposing this sort of regulatory interaction between the FDA and the ATF. A similar relationship was proposed by the Food Safety and Inspection Service (FSIS) of the USDA with respect to health claims for meat and poultry. Prior to 1994, the FSIS did not allow meat and poultry product labels to include health claims explicitly linking the consumption of these foods to diet-related diseases but instead only permitted label statements which informed consumers that a specific food could be part of a diet which met the general U.S. Dietary Guidelines. However, in response to the FDA's approval of health claims for food, the FSIS proposed a rule which would result in the adoption of regulations which would parallel those promulgated by the FDA for food health claims on meat and poultry.<sup>89</sup>

The FSIS stated that its was proposing a system which paralleled the FDA system because it felt that it is important to communicate consistent messages about dietary goals, and about the role meat and poultry products can play in meeting dietary recommendations to consumers.<sup>90</sup> While the FSIS did consider the possibility of merely permitting the use of all health claims already authorized by the FDA, it instead decided to propose its own regulations. However, the FSIS did state that it intended to rely heavily on FDA's decisions about the validity and significance of the relationship between the substances and diseases that are subjects of this proposal, and [will] continue to do so for future claims.<sup>91</sup> Thus, the FSIS proposed to

<sup>89</sup> 59 F.R. 27144 (May 25, 1994).

<sup>90</sup> *Id.* at 27150.

<sup>91</sup> *Id.* at 27146.

authorize health claims for meat and poultry products based on prior FDA scientific analysis.<sup>92</sup>

The system proposed by the FSIS parallels the FDA system in several respects. For example, the FSIS stated that it would use the FDA definition of what constituted a health claim, the FDA 10 percent RDV nutrient level rule for prohibiting health claims, the FDA definition of 'high in' nutrient levels for establishing minimum qualifying levels, and the FDA policy of allowing producers to petition the agency for approval of health claims by submitting proposed label statements with supporting scientific evidence. Thus, the FSIS basically proposed to adopt the FDA system of health claim regulation wholesale without any real significant change. Based on this action, it appears logical for the ATF to do the same for the labeling of health claims on alcoholic beverages. In fact, perhaps the ATF should merely defer to the FDA health claim regulatory system, as the FSIS had considered doing, because the ATF already does so for other scientific determinations related to the labeling of alcoholic beverages.

### **C. Application of the FDA Regulatory Policy and the FDMA Provisions**

If the ATF were to defer to the FDA on the labeling of health claims for alcoholic beverages, any health claim would have to meet the requirements of the FDA health claim regulatory system. As shown by the FDA's limitation of dietary fiber health claims to CHD, rather than the broader CVD, and the refusal to allow the scientific evidence supporting

<sup>92</sup> Specifically, the FSIS proposed to allow health claims related to the association between the following:

adequate calcium intake and reduced risk of osteoporosis, diets low in fat and reduced risk of cancer, sodium reduction and reduced risk of high blood pressure, reduction in dietary saturated fat and cholesterol and reduced risk of coronary heart disease, diets low in fat and high in fiber containing grain products, fruits, and vegetables, and reduced risk of cancer, diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain dietary fiber and reduced risk of coronary heart disease, substances in diets low in fat and high in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C) and reduced risk of cancer, and folate and reduced risk of neural tube birth defects. *Id.*, at 27 147-48.



the oat bran health claim to support claims for other soluble fibers, the FDA would probably only permit a claim which was narrowly tailored to rely on the strongest possible scientific evidence. While the CEI/CA suit argues that there is a consensus for the claim that the moderate consumption of all alcoholic beverages is associated with reduced risks of CHD, the strongest consensus and greatest volume of research relates to the claim that moderate consumption of wine is associated with reduced risks of CHD.<sup>93</sup> Thus, it should be easier to support a health claim on wine than any other alcoholic beverage.

A second requirement for a health claim which is evident from the FDA regulation of the dietary fiber health claim is that the health claim be placed in the context of general dietary recommendations. This is in fact what the U.S. Dietary Guidelines already does with respect to alcoholic beverages by virtue of the fact that the Guidelines state that there is evidence to suggest that moderate drinking of alcoholic beverages is associated with a lower risk of CHD. The fact that the Guidelines is designed to provide the public with information about what the government considers to be a healthy diet, in effect, places this link within the context of the general dietary recommendations of the U.S. government.

In fact, the Wine Institute, a winery trade association, has proposed label statements which would read 'To learn the health effects of moderate wine consumption, send for the federal government's Dietary Guidelines for Americans.'<sup>94</sup> While this proposal has been

*See, e.g., Renaud, S., and DeLorgeil, M., Wine Alcohol, Platelets and the French Paradox for Coronary Heart Disease, 339 The Lancet 1523 (1992); Kondo, K, et al., Inhibition of Oxidation of Low-Density Lipoprotein with Red Wine, 344 The Lancet 1152 (1994); Fuhrman, B., et al., Consumption of red wine with meals reduces the susceptibility of human plasma and low density lipoprotein to lipid peroxidation, 61 American Journal of Clinical Nutrition 549 (1995).*

Anderson, Curt, *Wine-label revision seen as pro-drinking*, Seattle Times (July 21, 1997).

opposed by groups such as the Center for Science in the Public Interest and the American Medical Association, ATF Director John Magaw is on record as saying that such a statement is neutral in tone, does not make claims about health and drinking, and would likely be approved.<sup>95</sup> Thus, any health claim for wine could state that the connection between moderate wine consumption and reduced risks of CHD only occur within the context of a diet that meets the U.S. Dietary Guideline recommendations. Such language would also address the FDA concern that any single food not be viewed as a magic bullet for preventing heart disease which the FDA noted in its regulation of the oat bran health claim.

Even if a health claim on wine did satisfy these standards, there are still several objections which could be made to such a claim. First, the word moderate may be viewed as not specific enough in that it does not convey a sense of how much alcohol is necessary to gain the beneficial health effects. However, scientific research has shown that the beneficial effects of wine result from the consumption of one to two 5 ounce drinks a day and that with more than two drinks per day there is a statistically significant increase in the incidence of cancer.<sup>96</sup> In fact, the U.S. Dietary Guidelines defines moderate consumption as no more than one drink per day for women and two drinks per day for men.<sup>97</sup> Thus, it is possible to precisely define the word moderate in a health claim for wine. And as the FDA action with regard to oat bran shows, the FDA has been willing to approve health claims even in the absence of officially defined DRV's.

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*Id*

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Camargo, C., et al., *Moderate Alcohol Consumption and Risk for Angina Pectoris of Myocardial*

*Infarction in US. Male Physicians*, 126 *Annals of Internal Medicine* 372 (March 1, 1997).

U.S. Dietary Guidelines, *supra* note 88, at 40.

Thus, the lack of an exact definition of moderate may not be as troublesome as it first appears.

A second objection to a health claim on wine is that this would encourage the consumption of a potentially dangerous product which has no real nutritional value. However, the U.S. Dietary Guidelines states that alcohol should not be consumed by children, adolescents, those of any age who cannot limit their intake, women who are trying to conceive or who are pregnant, individuals who plan to drive or take part in activities requiring attention and skill, and individuals using prescription and over the counter medicines.<sup>98</sup> Thus, the statement referring to the U.S. Dietary Guidelines which places wine consumption within the context of a healthy diet also would serve to alert those who should not drink about the dangers of doing so. This seems sufficient given the approval of shortened health claims that contain references to the location of complete information in the regulation of the oat bran health claim. The Guidelines also explicitly states that alcoholic beverages supply calories but few or no nutrients.<sup>99</sup> Thus, again this information would be accurately conveyed by a reference to the Guidelines. And as the regulation of the general dietary fiber health claim shows, the FDA is willing to approve health claims for foods that do not necessarily meet RDV's or that have limited nutritional value.

This leads to a final objection to a health claim for wine. This would be that because the mechanism by which wine supposedly reduces the risk of heart disease is not precisely understood, it cannot really be proven and distinguished from other mechanisms which might be at work in wine or other alcoholic beverages. Thus, as was the case with oat bran and psyllium

<sup>98</sup> *Id.*, at 41.

~ *Id.*, at 40.

fiber, the FDA should not permit a health claim until it is possible to prove the health effects of

each individual alcoholic beverage. However, scientific research has begun to suggest that the organic compound resveratrol, a naturally occurring fungicide present in many plants including wine grapes, may be the substance in wine which improves human cholesterol profiles and thus reduces the risk of CHD.<sup>100</sup> Furthermore, any health claim for wine could be qualified with the word 'may' to reflect the multi-factor nature and possible ambiguity of the association between wine consumption and reduced risk of CHD as was done with the oat bran health claim. This would also accurately reflect the U.S. Dietary Guidelines statement that current evidence *suggests* an association between alcoholic beverage consumption and reduced risks of CHD.

Given the FDA regulatory policy toward health claims on food, it appears that a health claim on wine labels which stated that

Scientific evidence suggests that there may be a connection between the moderate consumption of wine, (defined as no more than one drink per day for women and two for men) within the context of a healthy diet as recommended by the U.S. Dietary Guidelines, and reduced risks of coronary heart disease,

would meet the FDA requirements for health claims as applied under the 1990 FDCA amendments. If that were not the case, however, the 1997 FDMA health claims provisions may provide an alternative ground for gaining approval for a wine health claim.

The FDMA amended §403(r)(3) of the FDCA by adding a new subparagraph which authorizes the use of health claims on food labels which have not been pre-authorized by the

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Siemann, B.C., *Natural Compound in Wine Can Lower Cholesterol Levels*, 43 American Journal of Enology Viticulture 49 (1992).

FDA.<sup>10</sup> There are four requirements which must be met in order to justify the use of such a

claim. These requirements are the following:

1) the claim must be published as an authoritative statement by a scientific body of the U.S. government with official responsibility for public health protection or human nutrition research or the National Academy of Sciences,

2) at least 120 days before the use of the claim on labels in interstate commerce, a notice of the claim and its authoritative basis must be submitted to the FDA,

3) the claim and the food must meet FDCA provisions under §403(r)(3)(A)(ii) requiring that the food does not contain any nutrient in an amount which increases the risk of disease, §403(a) prohibiting false or misleading claims, and §201(n) defining misleading labeling, and

4) the claim must be stated in a manner that accurately represents the authoritative statement and enables the public to comprehend the information and to understand its significance in the context of a total daily diet

Under the new FDCA §403(r)(3)(D) introduced by the FDMA, a claim which meets the above requirements can be used on food labels until either the FDA issues a regulation stating that, or a U.S. District Court determines in an enforcement proceeding that, the health claim does not meet the requirements of statutory provisions.

It may be the case that the U.S. Dietary Guidelines statement that scientific evidence suggests a link between moderate consumption of alcohol and reduced risks of coronary heart disease would qualify as an authoritative statement of a U.S. government scientific agency responsible for human health under the new §403(r)(3)(C). While the USDA may not be a scientific agency, the Guidelines were established by direction of the National Nutrition

o~ FDCA §403(r)(3)(C).

Monitoring and Related Research Act of 1990.<sup>102</sup> This act states that the Guidelines shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.<sup>103</sup> Thus, it seems at least arguable that the Guidelines do constitute an authoritative scientific statement of the U.S. government in which case they would provide sufficient grounds for making a health claim on wine without waiting for direct FDA or ATF regulatory approval.

In fact, §403(r)(3)(C) was added to the FDCA by Congress precisely because of the regulatory delay in approving health claims. The House Committee Report stated that a primary motivation for the new statutory provisions was the substantial delay which had occurred in the FDA's approval of the health claim connecting folic acid and neural tube defects. While the Center for Disease Control had initially recommended that women of childbearing age consume folic acid in order to help prevent neural tube defects in September of 1992, the FDA did not issue a ruling for health claim labeling to this effect until March 1996. Thus, Congress felt that it was important to establish a mechanism by which there would be a presumption of validity with respect to claims that are appropriately based on statements by such authoritative scientific bodies in order to facilitate public access to health information.<sup>104</sup> Given the ATF's intransigence in approving a health claim for wine labels despite the overwhelming scientific evidence suggesting a link between its moderate consumption and reduced risks of CHD, the new statutory provisions might justifiably be read as covering a wine health claim as well.

<sup>102</sup> ~ USCS §5301, et seq.

<sup>103</sup> ~ USCS §5341(a)(1).

<sup>104</sup> ~ H.R. Rep. No. 105-306 (1997), at 14-16.

**Conclusion**

The FDA and the ATF have a long history of intertwined and often conflicting jurisdiction over the regulation of alcohol labeling. While they do seem to have reached a jurisdictional peace in which the ATF retains primary control over alcohol labeling while utilizing the FDA's scientific expertise, it may be time for another skirmish between the two. For it is clear that the ATF has been dragging its feet with respect to a potential health claim noting a connection between the moderate consumption of wine and reduced risks of CHD. The FDA health claim regulatory structure would provide a much more transparent framework in which a scientific debate over the merits of such a claim could occur. The most recent modifications of the FDCA show a clear Congressional intent to facilitate the use of health claims on food labels throughout the food supply. Thus, perhaps it is time to end the ATF's use of its regulatory power to stifle the consideration of a health claim on wine.